



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Pat nt and Trademark Offic**

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Washington, D.C. 20231

*DK*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/219,442    12/23/98    HU    J    PF112P2D1

022195    HM22/0919  
HUMAN GENOME SCIENCES INC  
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ROCKVILLE MD 20850

EXAMINER

SAOUD, C

ART UNIT	PAPER NUMBER
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1647

*14*

DATE MAILED:    09/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.  
**09/219,442**

Applicant(s)

**HU et al.**

Examiner

**Christine Saoud**

Group Art Unit

**1647**



☒ Responsive to communication(s) filed on Jul 10, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 33-446 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 33-446 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### Status of Claims

1. Claims 1, 22-24, and 26-32 have been canceled and claims 347-446 have been added as requested in the amendment of paper #12, filed 10 July 2000. Claims 33-446 are pending in the instant application.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 33-446 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

MPEP 2173.05(n) states that “[a]n unreasonable number of claims, that is, unreasonable in view of the nature and scope of applicant’s invention and the state of the art, may afford a basis for a rejection on the ground of multiplicity. A rejection on this ground should include all the claims in the case inasmuch as it related to confusion of the issue.” The instant application now contains 414 pending claims. In view of the nature and scope of the invention, directed to a polypeptide, compositions thereof, and methods of use, 414 claims is deemed to be unreasonable. Applicant should select 50 claims for the purpose of examination.

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Applicant is directed to issued patent 5,932,540 in which the currently claimed subject matter has already been allowed. The instant claims repeat what is already claimed and patented. The instant claims further are directed to the same polypeptide and many of the claims do not further limit the polypeptide that is being claimed. For example, the protein which is recovered from "a natural source" will not differ, however, there are 20 claims directed to a protein which is recovered from "a natural source". There are claims which are directed to protein which is recovered by (1) chromatography and (2) an antibody. However, these methods of recovery do not place any further limitations on the protein that is recovered; the protein is the SAME. Claim 113 is to a purified protein expressed from ATCC Deposit No. 97149 - it is not clear how this protein differs from the protein of either of claims 73 or 93. The claims include those which are directed to protein which "is recovered from a recombinant host cell engineered to express the protein" which already depend from purified protein claims wherein the protein is expressed in a host cell and recovered (see claims 205 and 207 for example). These do not appear to be further limiting and only add to the multiplicity of the claims.

Based on the 186 claims which have already issued in '540 and the pending 414 claims of the instant application, it appears that an unreasonable number of claims, that is, unreasonable in view of the nature and scope of applicant's invention and the state of the art, affords a basis for a rejection on the ground of multiplicity. Therefore, the claims are rejected for the reasons provided above.

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4. The method claims of this application conflict with claims 22-110 of Application No. 09/107,997. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

***Terminal Disclaimer***

5. The terminal disclaimer filed on 10 July 2000 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 5,932,540 has been reviewed and is NOT accepted.

6. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34

(a). See 37 CFR 1.321(b) and/or (c).

***Conclusion***

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

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Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 15, 2000

CHRISTINE SAOUD  
PATENT EXAMINER  
*Christine Saoud*